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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,990	01/22/2001	Jerome Besse	P66226US0	4037

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/06/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/764,990

Applicant(s)

BESSE JEROME ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Applicant's amendment, filed on July 28, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 32-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busciglio (U.S. Patent 4,748,022) in view of Santus et al. (U.S. Patent 6,333,044).

Busciglio provides a composition and method for the treatment of ulcers on mucosal surfaces resulting from chemotherapy, said compositions comprising propolis (See col. 2, lines 38-59 and col. 3, line 21 to col. 4, line 38). Busciglio reports that flavonoids are present in bee propolis (See col. 1, line 65 to col. 2, line 2) and teaches that the healing action of propolis is due to the presence of flavonoids in the propolis (See col. 4, lines 65-68). Busciglio teaches that the composition is a liquid for ease of administration throughout the mucous membrane, but also contemplates the presence of a gel base and thickening agents in the composition (See col. 4, lines 43-64 and col. 5, lines 1-11).

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Thus, with respect to claims 32, 34 and 35, Busciglio provides a method for the treatment of chemomucositis comprising administering a composition comprising flavonoids and a vehicle, and contemplates the presence of thickening agents in the composition of the invention.

Busciglio is deficient in the sense, that the patent does not include a viscosity modifier in the composition, such as a temperature-sensitive polymer, which would cause the solution to gel once applied to the mucous membrane.

Santus et al. discloses therapeutic compositions suitable for intranasal (mucosal) administration and teaches that the compositions of the invention may include polymers capable of conferring bioadhesive characteristics to the vehicle (See col. 2, line 66 to col. 3, line 38) and poloxamers, which make it possible to obtain low viscosity solutions at room temperature and increase in viscosity at body temperature, yielding a viscous fluid that ensures a better and longer contact with the mucous membrane (See col. 3, lines 50-61).

With regard to claims 33 and 34, the prior art does not specifically teach that the compositions are applied before chemotherapy, however, one of ordinary skill in the art, in view of the teachings of Busciglio, which discloses the oral lesions caused by chemotherapy (See col. 2, lines 38-41), would have applied the composition prior to chemotherapy to minimize the damaging effect of the chemotherapy on the mucous membrane and protect the tissue from said damaging effect..

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Regarding claims 36 and 38, Santus et al. discloses compositions comprising 0.05-2% of an agent conferring viscosity (See col. 3, lines 34-38 and col. 4, lines 35-42). The range disclosed by the prior art is within the range claimed by Applicant. The reference is silent regarding the amount of poloxamer to be included in the composition, however, Santus et al. provides the general teachings, that adjustments in the viscosity of the formulations, including addition of optional ingredients, can be made by the artisan skilled in the art (See col. 4, lines 44-53). Thus, one of ordinary skill in the art would have been capable to determine the optimal amount of the viscosity-modifying agent by routine experimentation.

With respect to claims 37 and 39, Santus et al. discloses poloxamers as temperature-sensitive polymers, which modify the viscosity of the composition (See col. 3, lines 50-61).

Regarding claims 40-42, Busciglio reports that flavonoids are present in bee propolis (See col. 1, line 65 to col. 2, line 2).

With respect to claim 43, the compositions disclosed by Santus et al. include water as vehicle (See Examples 1-9).

Regarding claim 44, the prior art is silent with respect to the viscosity of the compositions, however, Santus et al. provides the general teachings, that the viscosity of the formulations of the invention can be optimized by one of ordinary skill in the art (See col. 4, lines 44-53).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions disclosed by Busciglio, by including in the composition a poloxamer, as taught by Santus et al., to obtain a liquid, easy to handle and administer composition, which gels after application, thus improving contact with the mucous membrane and controlling the rate of release of the flavonoids in the composition. The expected result would have been a successful composition and a successful method of treatment comprising administering said composition. Because of the teachings of Busciglio, that the liquid composition of the invention includes thickening agents and a gel base, and the teachings of Santus et al., that better and longer contact with the mucous membrane can be obtained by including a poloxamer to modify to viscosity of the composition upon application, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in the treatment of chemomucositis. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

3. Applicant's amendment has overcome the 35 U.S.C. 112, first paragraph rejection of claims 20-28, 30 and 31 of the previous Office action.

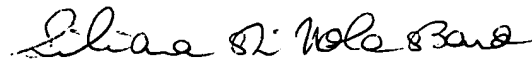
4. Claims 32-44 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.



October 2, 2003

Liliana Di Nola-Baron
Patent Examiner
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